907 KAR 1:350. Coverage and payments for organ transplants.

RELATES TO: KRS 205.520, 42 C.F.R. 447.53

STATUTORY AUTHORITY: 194A.030(2), 194A.050(1), 205.520(3)

NECESSITY, FUNCTION, AND CONFORMITY: The Cabinet for Health and Family Services has responsibility to administer the Medicaid Program. KRS 205.520(3) empowers the cabinet, by administrative regulation, to comply with any requirement that may be imposed, or opportunity presented, by federal law to qualify for federal Medicaid funds. This administrative regulation establishes provisions related to Medicaid Program coverage of organ transplants for Medicaid recipients and related to Department for Medicaid Services' reimbursement regarding organ transplants provided to Medicaid recipients who are not enrolled with a managed care organization.

Section 1. Definitions. (1) "Department" means the Department for Medicaid Services or its designee.

- (2) "Emergency" means that a condition or situation requires an emergency service pursuant to 42 C.F.R. 438.114(a).
 - (3) "Enrollee" means a recipient who is enrolled with a managed care organization.
- (4) "Experimental" means that a procedure has not previously been proven effective by the U.S. Food and Drug Administration in treating a patient's health condition.
- (5) "Managed care organization" means an entity for which the Department for Medicaid Services has contracted to serve as a managed care organization as defined in 42 C.F.R. 438.2.
- (6) "Medical necessity" or "medically necessary" means that a covered benefit is determined to be needed in accordance with 907 KAR 3:130.
- (7) "Nonemergency" means that a condition or situation does not require an emergency service pursuant to 42 C.F.R. 438.114(a).
 - (8) "Recipient" is defined by KRS 205.8451(9).

Section 2. Prior Authorization. (1) Prior to coverage of an organ transplant to a recipient who is not an enrollee, the transplant shall have been determined by the department to be:

- (a) Medically necessary; and
- (b) Clinically appropriate pursuant to the criteria established in 907 KAR 3:130.
- (2) The requirements established in subsection (1) of this section shall not apply to an emergency service.

Section 3. General Coverage Criteria. A covered organ transplant shall meet the criteria established in this section. (1) A transplant surgeon's opinion shall conclude that failure to perform the transplant would create a life-threatening situation.

- (2) The patient's prognosis shall indicate that there is a reasonable expectation the transplant will be successful and result in prolonged life of quality and dignity.
 - (3) The hospital where the transplant will take place shall:
- (a) Have a staffed and functioning unit designed for and accustomed to performing the planned organ transplant;
 - (b) Be accredited by the Joint Commission on Accreditation of Healthcare Organizations; and
 - (c) Be in good standing:
 - 1. If it is an in-state hospital, with the Cabinet for Health and Family Services; or
 - 2. If it is an out-of-state hospital, with that state's licensure authority.
- (4) The physician performing the transplant shall be recognized as competent by the medical community.

Section 4. Reimbursement for Organ Transplants. For an organ transplant provided by a:

- (1) Hospital to a recipient who is not an enrollee, the department shall reimburse as established in:
 - (a) 907 KAR 10:825 through September 30, 2015; or
 - (b) 907 KAR 10:830 effective October 1, 2015; or
- (2) Physician to a recipient who is not an enrollee, the department shall reimburse in accordance with 907 KAR 3:010.

Section 5. Noncovered Services. The department shall not approve a request for an organ transplant if the requested transplant:

- (1) Fails to meet the criteria of Sections 2 or 3 of this administrative regulation; or
- (2) Is experimental in nature.

Section 6. Not Applicable to Managed Care Organizations. A managed care organization shall not be required to reimburse for an organ transplant according to this administrative regulation. (13 Ky.R. 1520; eff. 3-6-87; Am. 15 Ky.R. 2462; eff. 8-5-89; 33 Ky.R. 600; 1563; eff. 1-5-2007; 40 Ky.R. 1488; 2298; eff. 5-2-2014; 41 Ky.R. 2136; 2559; eff. 7-6-2015.)